UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

October 31, 2012

Joseph J. Green
Counsel to the Copper Development Association
Kelly Drye & Warren LLP
Washington Harbour, Suite 400
3050 K Street, NW
Washington, D.C. 20007-5108

Dear Mr. Green:

Thank you for your letter of September 17, 2012, to Acting Assistant Administrator Jim Jones in which you requested a meeting to discuss some public health claims which you believe are being made regarding certain treated articles.

We were pleased to meet with you, Dr. Harold Michels and Mr. Peter Salero on October 23, 2012, to listen to your concerns and to discuss how EPA could address them. As Mr. Bill Jordan, Deputy Director, Office of Pesticide Programs, stated, the Antimicrobials Division will make every effort to resolve your concerns. In addition, we recommended that you contact Mr. Brian Joffe, Chief, Pesticides and Toxics Enforcement Branch, Office of Enforcement and Compliance Assurance, with respect to any questions you may have about enforcement. Finally, you raised a number of questions about a competitor's registered product and indicated that you would submit those questions to the Antimicrobials Division for our consideration.

We look forward to receiving your questions and addressing them. If you have any other concerns, please feel free to contact me (703-603-8414; harrigan-farrelly.joan@epa.gov).

Sincerely,

Joan Harrigan-Farrelly
Director, Antimicrobials Division

cc: James Jones
Steven Bradbury
William Jordan
Jennifer McLain
Brian Joffe


Copper Development Association Inc.
Copper Alliance

November 2, 2012

Joan Harrigan-Farrelly
U.S. Environmental Protection Agency
Director, Antimicrobials Division
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**Re: Submission of Information Concerning Inadequate Efficacy Data and Request to Reconsider Registration for "Antimicrobial Cupron Enhanced EOS Surface" (EPA Reg. No. 84542-7)**

Dear EPA:

On behalf of the Copper Development Association ("CDA"), we hereby submit information and questions concerning the registration of "Antimicrobial Cupron Enhanced EOS Surface" ("Cupron/EOS Surface") (EPA Reg. No. 84542-7). In short, fundamental questions regarding the efficacy of the Cupron/EOS Surface, including the long-term durability and antibacterial performance of the product, must be addressed before the agency should allow the continued marketing and sale of this "public health" product intended to fight infection-causing bacteria in the healthcare environment and other settings. To do otherwise would pose a risk to the health of patients, users, and other consumers who rely on the "public health" antibacterial claims made for the product. While the issues discussed below remain unanswered, it would be arbitrary and capricious for the U.S. Environmental Protection Agency ("EPA") to conclude that the efficacy of the Cupron/EOS Surface has been demonstrated. Accordingly, under its FIFRA authority (7 U.S.C. §136a(g)(1)(B), §136d(b), §136d(c)(1)), EPA should reconsider and cancel or suspend the registration at this time pending resolution of these critical issues.

During the over four year registration process for Antimicrobial Copper Alloys (EPA Reg. Nos. 82012-1 through -6), which contain 60-99.9 percent copper, EPA developed new protocols to test the efficacy of these novel antimicrobial materials – solid metal surfaces with inherent antimicrobial properties (in comparison to more traditional antimicrobial sprays and similar treatments). While new to FIFRA, these metal alloys are the same brass, bronze, and numerous other copper-based alloys that have been manufactured to strict industrial specifications for many decades. Each alloy must meet the chemical specifications detailed in the

ASTM Unified Numbering System ("UNS") for the durable life of the product. Because the copper and other metals that comprise the alloys are metallically bonded within a crystalline matrix, the chemistry of the alloy does not change over time. Accordingly, because the alloy chemistry does not change over time, the antimicrobial efficacy of Antimicrobial Copper Alloys is properly assessed by the two- and 24-hour testing. The long-term efficacy results were verified by testing a variety of older copper alloy products (such as doorknobs and pennies). In addition, real world efficacy has been confirmed through recently concluded clinical trials performed under the auspices of the U.S. Department of Defense.

Before registration was granted to Antimicrobial Copper Alloys, EPA required outreach to pose questions to experts in the infection control community, including the Association for Professionals in Infection Control and Epidemiology ("APIC"), the American Society for Healthcare Environmental Services ("ASHES"), Dr. William Rutala from the University of North Carolina-Chapel Hill, and others. The input received was critical in shaping the conditions and requirements of the registration and, significantly, in helping inform the agency of various efficacy questions to be asked of the product before registration should be granted. The issues raised included questions about the long-term efficacy of the product, the potential impact of various cleaning agents on the product, and the need for proper education and stewardship. APIC specifically raised critical points regarding the durability of the surface material and the need for clinical trial data. These points were addressed and resolved before the CDA registrations were issued.

Unfortunately, it does not appear that these same fundamental questions were asked of the Cupron/EOS Surface product. As a result, there remain critical unanswered questions about the long-term efficacy and durability of the product, as well as the product's suitability for the applications for which registration was granted. These issues are explained in detail below, with relevant questions highlighted.

**(1) The Efficacy Test Protocols Were Not Designed to Assess the Performance of a Material That Changes Chemically Over Time**

Unlike a sanitizing spray or similar antimicrobial treatment, which have an immediate but short-term sanitizing or disinfecting effect, an antimicrobial solid surface is intended to continually reduce bacterial load during the useful life of the product, which can be a decade or longer (such as a countertop in a hospital or home). Accordingly, to demonstrate

efficacy for solid metal materials, the three testing protocols are based on the presumption that the tested material will remain chemically and physically consistent during the useful life of the product. The consistency of copper alloys in this regard has been demonstrated for decades under the ASTM/UNS program, which guarantees the chemistry of the alloy. No such guarantee or demonstration has been made for the Cupron/EOS Surface. Accordingly, the antibacterial performance of the Cupron/EOS Surface over the two- and 24-hour testing protocols does not support efficacy over a longer period of time, and, therefore, does not support the efficacy of a product with an expected useful life of many years. Long-term efficacy of the product must be demonstrated through the development and use of new, more appropriate test protocols.

***Question: How fast are the active copper ions depleted from the cuprous oxide on the surface?***

***Question: What is the long-term viability and efficacy of the cuprous oxide?***

***Question: What test protocol may be used to demonstrate long-term antimicrobial durability and efficacy of the product?***

**(2) Long-Term Efficacy and Durability of the Cupron/EOS Surface Has Not Been Demonstrated**

The Cupron/EOS Surface consists of copper oxide particles (16 percent cuprous oxide by weight, or approximately 14 percent copper) that are impregnated into a polymeric substrate from which copper ions leach. The copper oxide particles, based on the densities of the active and inert ingredients, comprise approximately less than three percent of the volume and surface area of the product. Based on a long history of testing, CDA is aware that copper alloys containing roughly 50 percent or less copper do not demonstrate efficacy under the testing protocols.

Polymeric matrices, by their nature, degrade and do not have the inherent structural or mechanical stability of solid copper alloys. Degradation of the polymer may result from chemical or hydrogen peroxide cleaning systems, as well as from photo-degradation (*e.g.*, from ultraviolet cleaning systems) and/or heat. The long-term stability and durability of the polymeric counter tops has not been demonstrated.

Most importantly, the antimicrobial performance of the Cupron/EOS Surface is based on the leaching of copper ions from the material. These ions leach out of the surface and eventually will be depleted. While rapid copper ion release may account for efficacy in the short term (such as under the two- and 24-hour testing protocols), the leaching action suggests a finite limit to the active ingredient contained in the polymeric substrate. Further, common cleaning agents may deplete the active ingredient on the surface.

Upon depletion, due to the encapsulation of remaining copper oxide particles in the polymeric substrate, no active ingredient will be available to take the place of the depleted particles at the surface – unless a significant portion of the polymer is worn away (which, if so, raises questions about the durability of the surface). Accordingly, long-term efficacy of the product is questionable and has not been demonstrated.

***Question: How, if at all, do the cuprous oxide particles embedded in the polymer matrix get to the surface, particularly after the surface particles are depleted of copper ions?***

***Question: Are the cuprous oxide ions active over the entire useful life of the product? How is this demonstrated, if at all?***

The phenomenon is similar to (cuprous oxide-containing) anti-fouling paint, which must be reapplied periodically as the copper ions are released and the antimicrobial efficacy of the paint depleted. In contrast, copper alloys, containing 60-99.9% copper, do not deplete and there is a near-infinite supply of copper available throughout the alloy matrix.

**(3) The Conditions of the Test Protocols Favor Surfaces That Leach the Active Ingredient**

As observed in commercial silver-containing coatings (Michels *et al.*, *Letters in Applied Microbiology* 49 (2009) 191–195), the efficacy of surface materials impregnated with antimicrobial additives, is highly dependent on the presence of moisture. At high levels of humidity, these products demonstrate some level of efficacy, while little to no efficacy is seen at normal or low levels of humidity. The wet inoculation method utilized in the solid surface testing protocols likely enhances the efficacy performance of the Cupron/EOS Surface by promoting more rapid leaching of the copper ions from the polymeric substrate and distribution of those ions

across the surface. Under dry conditions, such as those involving the transfer of bacteria from contaminated hands, which are more likely to be experienced in hospital settings or the home, the copper ions would not be expected to be transported across the product surface as readily, resulting in reduced efficacy. [In contrast, the performance of copper alloys is not dependent on the transport of copper ions across the surface, as the high percentage of copper in the alloy results in direct bacterial contact with the copper.]

***Question: How does the Cupron/EOS Surface, which is dependent on the spreading of copper ions across the surface, perform under dry inoculation test conditions?***

***Question: Will the copper ions be released in the typical dry environment?***

***Question: Under typical (dry) environmental conditions, how do the copper ions (which represent approximately three percent of the product surface area) impact the remaining 97 percent of the surface area that is comprised of inert ingredients?***

**(4) The Potential for Formation of Resistant Organisms Should Be Examined**

As noted above, the relatively small amount of active ingredient – approximately less than three percent by volume and surface area – in the Cupron/EOS Surface means that large areas of the product may serve as havens for bacteria. While some bacteria would encounter the copper ions leached from the Cupron/EOS Surface – particularly, as discussed above, when the ions are spread across the surface during the wet inoculation method used in the testing protocols – many bacteria would be expected to be present in the approximately 97 percent of the surface that is non-copper. Organisms that reside on surfaces with lower concentrations of copper ions, or none at all, may receive a sub-lethal dose. Prolonged exposure to a sub-lethal dose of copper ions increases the potential for development of microbial resistance. Depletion of copper ions over time, as discussed above, is likely to exacerbate this potential risk.

***Question: Has the issue of the potential formation of copper-resistant organisms been examined? How can the registrant guarantee that resistance will not develop given the potential for delivery of sub-lethal doses of copper***

***ions as the ions are depleted and/or bacteria reside on the non-copper polymer portion of the surface?***

**(5) How Is the Product Chemistry Guaranteed?**

While Cupron/EOS indicate that the manufacturing process results in the uniform distribution of the active ingredient throughout the polymeric substrate, it is unclear how this guarantees a uniform concentration of copper ions at the surface level. How can consistent concentrations of cuprous oxide at the surface be guaranteed by the manufacturer, particularly across different manufacturing lots?

Moreover, downstream processing activities – such as buffing or polishing to achieve a semi-gloss finish, cutting, grinding, or forming into different shapes – would be expected to generate heat that could affect the polymeric substrate. This could cause the polymer to spread and coat the cuprous oxide, rendering it unavailable for contact with bacteria.

The EOS "fabrication manual" (available at a link at http://eos-surfaces.com/eos/commercial/) indicates that "the finish delivered to the fabricator is a 'factory finish,' and not a final finish. EOS Fabrication Manual at 102. The fabricator is required to use 'standard solid surface finishing steps' to create the desired finish." One option is a semi-gloss finish. CDA is concerned that the inherent heat associated with abrasion finishing techniques could alter the finish from the one that EPA evaluated in the tests submitted; and that there are no controls over how a surface finish (and hence efficacy) can be affected by an installer/fabricator. In fact, EOS expressly disclaims responsibility for the finish in its product warranty: "EOS™ Surfaces LLC does not warranty finishes, it is the responsibility of the fabricator to provide a proper finish to the consumer." EOS Fabrication Manual at 77. These issues and concerns do not exist with copper alloys.

***Question: How does the registrant guarantee the batch-to-batch consistency of the Cupron/EOS Surface?***

***Question: How is chemistry certified? Under what universally-accepted standard?***

***Question: What assurance is there that the chemistry and performance of the Cupron/EOS Surface does not change throughout the manufacturing and fabrication processes? After downstream processing and finishing?***

**(6) There Is a Disconnect Between the Directions for Use and the Functioning of the Product**

The Directions for Use state that the product must not be "coated" in any way. The purpose of this instruction is to prevent the formation of a barrier between the active ingredient and bacteria. Yet with the exception of a finite amount of cuprous oxide on the surface, the remaining active ingredient is encapsulated by the "non-porous" polymeric substrate and unavailable to replenish the cuprous oxide that will be depleted of copper ions over time (as discussed above). The EOS/Cupron website makes this point clear, stating that "[t]hese copper oxide-infused polymers are embedded into the material." (http://eos-surfaces.com/cupron/)

***Question: How can the copper ions be available if the cuprous oxide is embedded in the polymeric substrate, particularly after the active ingredient is depleted at the surface?***

**(7) The Cleaning Instructions Are Contrary to the Required Claim Language**

The product label includes mandated language, qualifying the basic antibacterial claims, that instructs users to "continue to follow all current infection control practices, including those practices related to cleaning and disinfection of environmental surfaces." Further, the Directions for Use state that "[c]leaning agents typically used for traditional touching surfaces are permissible; the appropriate cleaning agent depends on the type of soiling and the measure of sanitization required." However, the Cupron/EOS website states that "strong acidic cleaners" should not be used on the product. (http://eos-surfaces.com/eos/residential/product-care/) A number of common hospital cleaning agents, as well as those used in the home, are acidic, some of which are highly so (such as those containing acetic acid and citric acid).

***Question/Issue: What effect will cleaners, acids, solvents, etc. have on the cuprous oxide? The Directions for Use must be amended to comport with the cleaning instructions that EOS/Cupron post on their website.***

In addition, the EOS/Cupron website includes an article entitled "Self-cleaning countertop?" The article further states that the countertop "essentially cleans itself." These statements are in clear contradiction to the mandated label language noted above, and the fundamental stewardship concept that the product is a supplement to, not a substitute for, routine cleaning procedures.

**(8) The Registration Should Be Specific to Countertops**

If the Cupron/EOS Surface registration is to continue, it should only be approved for countertops. From the available information, it appears that only slab material used to make EOS Surface countertops was evaluated; there is no information regarding manufacture of the product into tubular and other forms. To make other forms entails different processing stages that can affect the chemistry of the final product. This is unlike copper alloys, which must meet ASTM/UNS specifications in any form in which the alloy is produced. In contrast, the polymeric base of the Cupron/EOS Surface can be altered through different processing stages. Accordingly, the performance of the material in slab/countertop form is not representative or a guarantee of performance in other forms (such as tubular railings, grab bars, hand rails, bed rails, cart handles, towel bars, exercise equipment, *etc.*). For this reason, the approved list of applications on the current label is overbroad and unsubstantiated.

In short, if allowed, the CuPron/EOS registration should be a ***product*** registration, and not a broad ***material*** registration, unless there is a universally (industry) agreed upon standard for certifying content, and unless the content can be assured not to change over the lifetime of the material. Unlike copper alloys that do not physically change by fabrication with the base metal, there is no evidence that all of the applications listed on the EOS registration are capable of being manufactured from the Cupron/EOS polymer matrix, nor that the processing requirements to manufacture these items would not alter the nature of the matrix and antimicrobial efficacy of the product.

* * * *

As the steward of Antimicrobial Copper that has worked diligently over the last several years to educate the public, and specifically the healthcare community, about the proper

use and role of antimicrobial copper products as part of an infection control program, CDA is concerned that the registration of a product, the Cupron/EOS Surface, with unproven long-term efficacy will undermine these stewardship efforts and cause substantial confusion. Fundamental unanswered questions exist regarding the efficacy of the product. These uncertainties pose risks to the health of consumers and users, particularly in the healthcare setting, who may rely on an ineffective product intended to help fight infection-causing bacteria. For these reasons, CDA requests that EPA cancel or suspend the registration pending resolution of the efficacy and other issues detailed above.

CDA appreciates and actively supports the efforts of EPA to promote a proper understanding of the role of antimicrobial products in addressing infection-causing bacteria. To do so effectively, the agency must ensure, as it has with Antimicrobial Copper Alloys, that fundamental questions of efficacy, chemistry, and durability are addressed for all solid surfaces that claim to be antibacterial. If you have any questions or would like further information, please contact CDA counsel, Joseph Green at 202.342.8849 or JGreen@KelleyDrye.com.

Respectfully submitted,

Andrew G. Kireta Sr.
President and CEO
Copper Development Association Inc.

cc: Jim Jones (Jones.Jim@epa.gov)
Steve Bradbury (Bradbury.Steven@epa.gov)
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Phil Ross (Ross.Phil@epa.gov)

**Fw: Complaint regarding Misleading and Unregistered Antimicrobial Public Health Claims - Cupron Technologies and EOS Surfaces**

**Karen Leavy** to: Brenda Mosley 10/09/2012 02:57 PM
Cc: edwards.dennis, Marshall Swindell

Brenda,

I went through my messages to Joe Green. Maybe I did NOT hit the send button; however, I don't understand how I sent him a message stating that his complaints had been sent to OCEA but you did NOT get them. It is a mystery to me. I did take those dates off the complaint chart.

KML
----- Forwarded by Karen Leavy/DC/USEPA/US on 10/09/2012 02:44 PM -----

| | |
|---|---|
| From: | Karen Leavy/DC/USEPA/US |
| To: | "Green, Joseph J." <JGreen@KelleyDrye.com> |
| Cc: | Dennis Edwards/DC/USEPA/US@EPA, Jennifer Mclain/DC/USEPA/US@EPA, Joan Harrigan-Farrelly/DC/USEPA/US@EPA, Marshall Swindell/DC/USEPA/US@EPA |
| Date: | 08/13/2012 02:09 PM |
| Subject: | Re: Complaint regarding Misleading and Unregistered Antimicrobial Public Health Claims - Cupron Technologies and EOS Surfaces |

Joe,

All of your complaints, as per the Stewardship plan as outlined in the registration notices for CDA's products, are forwarded to OECA. I will check with Dennis about your concerns below. I will forward the information below to OECA.

Thanks,

KML

-----"Green, Joseph J." <JGreen@KelleyDrye.com> wrote: -----
To: Dennis Edwards/DC/USEPA/US@EPA, Marshall Swindell/DC/USEPA/US@EPA, Joan Harrigan-Farrelly/DC/USEPA/US@EPA
From: "Green, Joseph J." <JGreen@KelleyDrye.com>
Date: 08/10/2012 01:43PM
Cc: Jennifer Mclain/DC/USEPA/US@EPA, Karen Leavy/DC/USEPA/US@EPA
Subject: Complaint regarding Misleading and Unregistered Antimicrobial Public Health Claims - Cupron Technologies and EOS Surfaces

*(See attached file: CDA Complaint to EPA - Cupron and EOS.pdf)*
*(See attached file: 084542-00005-20110510.pdf)*
*(See attached file: EOS_Cupron Brochure.pdf)*
*(See attached file: EOS Booth HCD11.pdf)*

Dear EPA -

In November 2011, I submitted the attached complaint on behalf of the Copper Development Association regarding misleading and unregistered public health antimicrobial claims made by Cupron Technologies and its partner, EOS Surfaces. (See attached) In doing so, we urged the agency to take action to these

misleading claims. We are unaware of any EPA action to do so, though hope that enforcement action is being pursued (and we understand that the agency is not at liberty to divulge enforcement activity to third parties). Nevertheless, CDA is concerned that the misleading claims continue to be made by EOS and Cupron - as evidenced by the article entitled "Antimicrobial Copper-Infused Countertop in The Hospitalist: New Infection-Control Weapons Emerge" recently posted on the EOS Surfaces website ( http://eos-surfaces.com/news).

The claims being made for these products are extremely dubious given the minimal amounts of copper infused into the surfaces (0.2-4% of total product weight) for which efficacy against public health organisms are claimed. In contrast, the EPA-registered Antimicrobial Copper Alloys contain 60-99.99% copper and are 100% composed of the registered alloys. Based on CDA expertise, any claims of efficacy against public health organisms by a product containing such miniscule amounts of copper is implausible.

In addition, unlike metals, treated surfaces wear down over time rendering questions about the durability about the product's claimed efficacy. Moreover, the consistency of product chemistry - particularly the consistency of the EOS Surfaces product that incorporates the Cupron additive is uncertain. With respect to Copper Alloys, chemistry is governed by a industry standard setting system (the UNS system) which guarantees the chemistry of the alloy. No such guarantee exists for an additive or coating.

Accordingly, CDA is deeply concerned about the claims being made for this product -- and the potential granting by EPA of a registration for the product by EPA for public health claims (according to statements on the EOS Surfaces website).

Please let me know if EPA is taking action to address these claims or if we should discuss our concerns with others at the agency or Department of Justice.

Thank you for your attention to this matter and do not hesitate to contact me if you have any questions or would like additional information.

Regards,

Joe

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Counsel to the Copper Development Association

**From:** Green, Joseph J.
**Sent:** Wednesday, November 16, 2011 12:33 PM
**To:** 'Edwards.Dennis@epamail.epa.gov'; 'Swindell.Marshall@epamail.epa.gov'
**Cc:** 'harrigan-farrelly.joan@epa.gov'; 'mclain.jennifer@epa.gov'; 'Leavy.Karen@epamail.epa.gov'
**Subject:** Complaint regarding Misleading and Unregistered Antimicrobial Public Health Claims - Cupron Technologies and EPS Surfaces

Dear Dennis and Marshall -

Attached please find a complaint submitted on behalf of the Copper Development Association regarding misleading and unregistered public health antimicrobial claims -- including most prominently in the healthcare environment - made by Cupron Technologies and its partner, EOS Surfaces. CDA is deeply troubled by these claims, in no small part because they misleadingly cite for support the extensive efficacy data developed by CDA for Antimicrobial Copper Alloys - data that is irrelevant to the potential efficacy of coatings infused with a small amount of copper or cuprous oxide particles.

CDA is committed to report to EPA misleading claims related to antimicrobial copper. CDA takes this obligation seriously and has been directing a multi-year effort to educate and inform potential users of the proper application and role of antimicrobial copper alloys in fighting bacteria that can cause infections and disease. Misleading statements such as those being made by Cupron and EOS undermine this effort and create confusion among the public. These concerns are compounded when they involve sensitive populations such as those in the healthcare environment.

CDA urges EPA to act forcefully to stop these misleading claims.

Please do not hesitate to contact me if you have any questions or would like further information.

Regards,

Joe

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CDA Complaint to EPA - Cupron and EOS.pdf

084542-00005-20110510.pdf

EOS_Cupron Brochure.pdf

EOS Booth HCD11.pdf

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November 16, 2011

*VIA ELECTRONIC MAIL*

Dennis Edwards, Branch Chief
Marshall Swindell, PM 33
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**Re: Misleading Claims by Cupron Technologies and EOS Surfaces**

Dear Mr. Edwards and Mr. Swindell:

In support of the registration of antimicrobial copper alloys, the Copper Development Association ("CDA") is obligated and committed to report to the U.S. Environmental Protection Agency ("EPA") misleading claims concerning the antimicrobial efficacy of copper. CDA is deeply concerned that Cupron Technologies ("Cupron") and its partner, EOS Surfaces, LLC ("EOS"), which markets products that incorporate Cupron "antimicrobial" additives, are making extensive unsubstantiated public health claims without EPA registration and in violation of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). CDA urges EPA to take immediate action to address these violations and stop the marketing and sale of products bearing misleading antimicrobial public health claims. These concerns are described in detail below.

## I. CUPRON MAKES EXPLICIT UNREGISTERED PUBLIC HEALTH CLAIMS AND IMPLIES HUMAN HEALTH PROTECTION FROM TREATED ARTICLES

Cupron has an EPA registration for "Cupron Cuprous Oxide 95" (EPA Reg. No. 85452-5; attached) that allows for a variety of articles, including countertops and a variety of

plastics and other coatings, to be treated with the product. The Directions for Use of the registration state:

> Cupron Cuprous Oxide provides bacteristatic and fungistatic protection to the final articles identified on this label. Manufactured products using Cupron Cuprous Oxide may not make any public health claims relating to antimicrobial activity without first obtaining an EPA registration for the manufactured product.

Unfortunately, Cupron makes explicit public health claims for their product and technology. For example, the Cupron website (www.cupron.com) includes the following statements:

- "Broad spectrum effectiveness against bacteria, viruses, mold, and dustmites."
- "In medical applications Cupron technology effectively deactivates (kills) a broad spectrum of microbes (bacteria, viruses, and fungus), specifically through the microbes exposure to copper ions."
- "The copper at the core of Cupron Technology is considered to be a very broad spectrum antimicrobial. As such, Cupron technology has been tested in medical applications and found to be effective in deactivating (killing) a broad range of bacteria (including MRSA), viruses (including influenza), fungus (including aspergillus niger), and even dustmites."
- "Reducing Healthcare Associated Infections (HAIs): In addition to helping healthcare facilities reduce HAI's and their related costs, Cupron Technology also has potential to help provide protection to healthcare workers and patients by reducing the chance of cross contamination through deactivating a broad spectrum of infection causing microbes (bacteria, viruses, and fungus). Cupron Technology can be embedded in a variety of woven and non-woven fabrics to potentially combat disease spread . . . ."
- "Copper provides antimicrobial protection against damaging microbes such as bacteria, fungi, and viruses. Many bacteria, fungus, and microbes can cause stains, odors and product deterioration."

This is only a sampling of the many explicit public health claims made by Cupron, none of which are registered by EPA and all of which are in clear violation of FIFRA and the approved label for EPA Reg. No. 85452-5. The website also includes a lengthy list of scientific articles regarding the antimicrobial properties of copper against a wide variety of public health organisms. Most of these studies misleadingly pertain to antimicrobial copper alloys which are solid materials that, unlike Cupron, have public health registrations with EPA.

Moreover, as exemplified in the last statement quoted above (found in the FAQ section of the website), Cupron fails to make clear that articles treated with its product offer no protection to human health. Instead, Cupron buries amid a flurry of explicit public health claims the traditional disclaimer that the additive only offers "product protection" to "treated articles."

## II. EOS MAKES UNREGISTERED PUBLIC HEALTH CLAIMS FOR HEALTHCARE AND OTHER SURFACES

Consistent with the example set by Cupron, EOS Surfaces makes a series of dramatic, yet unregistered, public health claims for its "Cupron Enhanced EOS Solid Surface" line of products. The product brochure (attached) includes public health claims such as:

- "Copper has natural antimicrobial properties that kills a range of bacteria, fungi and viruses."
- "EOS Solid Surface is able to offer hospitals, schools, hospitality and homeowners a defense against the rising tide of the planets' microbes."
- "Each sheet of Cupron Enhanced EOS Solid Surface is infused with Cupron technology on all exposed surfaces. Hence, no matter where the sheet is cut, or what part of the sheet is exposed, the Cupron is there to kill the microbes that land on it."
- "Cupron Enhanced EOS Solid Surface is not only a powerful potential disease prevention tool, but a sensible economic investment."

The brochure even includes an extensive list of public health organisms that "Cupron Technology has been proven to kill":

**Bacteria**
Pseudomonas aeruginosa
Enterococcus faecal is (VRE)
Escherichia coli (E. coli)
Staphylococcus aureus (MRSA)

**Fungus**
Tricophyton rubrum (foot fungus)
Candida albicans
Aspergillus niger

**Virus**
HIV 1
Influenza (HI N1) (Swine flu)
Measles

The brief mention in the brochure that Cupron offers "antimicrobial product protection" is negated by the overwhelming number of explicit public health claims made for the product.

Moreover, to support the antimicrobial efficacy of the product, the EOS brochure misleadingly cites the public health registrations obtained by CDA for Antimicrobial Copper *Alloys*:

> "In 2008 the US Environmental Protection Agency registered 275 copper alloys with Public Health claims. The registration means that the EPA recognizes the antimicrobial properties of copper. All Public Health claims must be supported by extensive testing under EPA protocols in an independent laboratory that adheres to OECD (Organization for Economic Cooperation and Development) Good Laboratory Practice guidelines."

This is a gross misuse of the efficacy data generated for Antimicrobial Copper Alloys at great expense to CDA. Solid copper alloys are entirely different products than coatings or additives that are incorporated into products such as the "Cupron Enhanced EOS Solid Surfaces." The EOS products incorporate a small amount of copper or cuprous oxide particles which, according to the Cupron EPA registration, ultimately equates to 0.2-4% of the final product weight. In contrast, the products for which copper alloys are approved for use are 100% of the registered Antimicrobial Copper Alloy (which contain 60-99.9% copper).

In addition to statements such as those made in the brochure, the EOS Solid Surface website (http://eos-surfaces.com/cupron/) includes numerous similar statements:

- "Cupron Enhanced EOS Solid Surfaces can benefit any individual or organization that provides a service where a reduction in bacterial and viral loads would be necessary or even preferred. Our protected solid surface is appropriate for any horizontal and/or vertical surface within your home; in a hospital, hotel, school, or military facility; and much more." (http://eos-surfaces.com/cupron/applications/)

- "With the surge in Hospital Acquired Infections (HAIs) and their rising costs to the healthcare industry, Cupron Enhanced EOS offers a real cost savings-based option to the healthcare system. HAIs are not covered by the patients' insurance and are a direct cost to a hospital's bottom line." (http://eos-surfaces.com/cupron/applications/)

- "By combining the extremely hygienic, non-porous nature of EOS Solid Surface with the tested, cutting edge technology of Cupron, Eos is able to offer hospitals, schools, military facilities, hospitality, and homeowners a defense against the rising tide of the planet's microbes." (http://eos-surfaces.com/cupron/how/)

- "Cupron Enhanced EOS, with Cupron, Inc., is engaged in ongoing consultation with the EPA. The company recently received approval for all of its testing protocols as well as approval for the use of Public Health Claims language for Cupron Enhanced EOS upon the completion of this final phase of testing. We will bring you updates as we proceed through the end stage of this process." (http://eos-surfaces.com/cupron/how/) (CDA is unaware of any efficacy data or testing that would support the public health claims touted by EOS or Cupron)

EOS also has been prominent at various trade shows touting the alleged public health benefits of its product. For example, at the Healthcare Facilities Symposium & Expo in Chicago on September 20, 2011, EOS had a prominent booth, as seen in the images below (images from EOS website: http://eos-surfaces.com/2011/09/eos-surfaces-launches-first-copper-oxide-infused-solid-surface-countertop/). The first image (panel on left) shows the EOS booth, which includes the list of public health organisms against which the Cupron technology used by EOS supposedly is effective.

Further, statements made by EOS representatives at the trade show were even more extreme than the public health statements made in the brochure and on the website. These statements included the following:

- EPA recognizes the antimicrobial properties of copper, and has registered copper alloys with public health claims.
- All public health claims are supported by extensive testing under EPA protocols in an independent GLP laboratory
- Cupron's technology has undergone extensive independent laboratory testing and has a long history of safe use.
- Cupron is registered with EPA (as a fiber preservative) and can be sold and marketed in the U.S. by official permission of the EPA.
- Cupron EOS Surfaces are a powerful potential disease prevention tool.
- Independent testing laboratories have demonstrated Cupron's efficacy in deactivating a wide variety of microorganisms.
- Cupron Technology has been proven to kill bacteria, fungi and viruses (and list MRSA, HIV 1, H1N1, plus a series of other bacteria including those included in CDA's registration).

Further, when asked about supporting efficacy data, the EOS representatives (including the company CEO) responded:

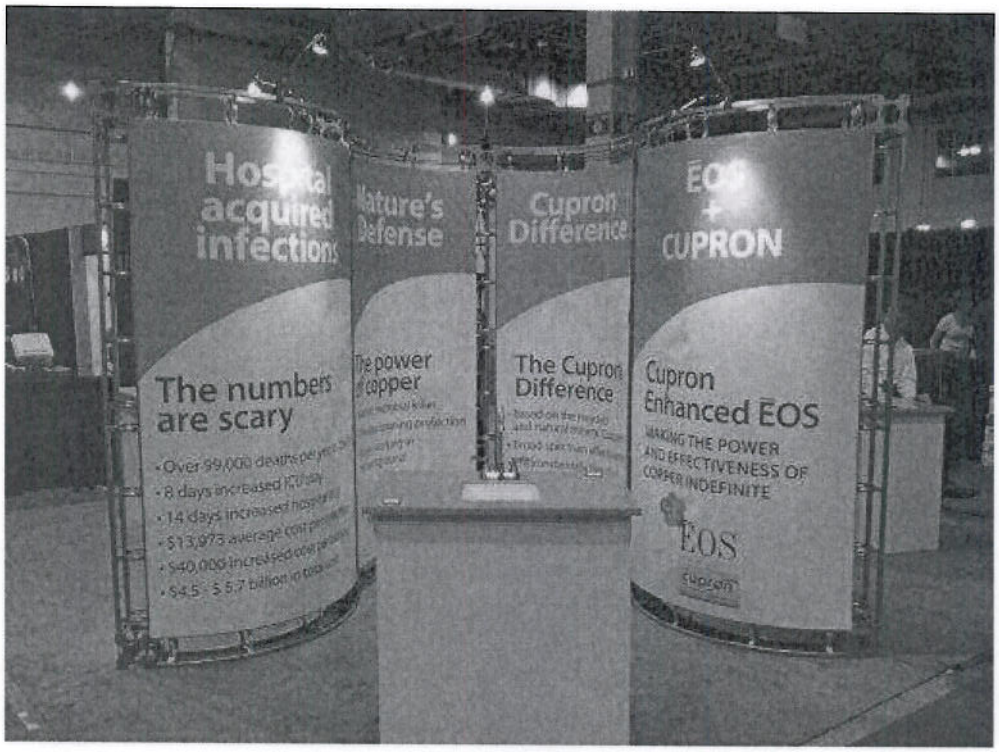
"Leave a card and we'll send you the test data."

"Clinical trials are underway, and results will be published on our website soon…keep checking."

"You should have been here yesterday when Cupron's scientific expert was here…he could have explained the clinical trials much better than me." (EOS CEO)

"We don't have EPA registration for public health claims yet, but EPA has approved copper, and ours will be coming in a few weeks for these surfaces."

There is a reason why EOS makes such claims – they are effective and, in fact, created a stir among conference attendees. CDA urges EPA to take action to stop these misleading claims and marketing activities.




## III. QUESTIONABLE EFFICACY OF "COATING" PRODUCTS

As noted above, efficacy data that support the public health registrations of Antimicrobial Copper Alloys are inapplicable to coating technologies that incorporate copper and copper-oxide particles into coatings, electroplatings, or other thin-film deposition processes such as flame spray or thermal spray. The same can be said for solid surfaces impregnated with copper or copper-oxide particles. The fact is that such coating technologies have not submitted to EPA, or even generated, relevant public health efficacy data.

Unfortunately, as exemplified above in the cited Cupron and EOS claims, there has been a proliferation of such unregistered claims being made for coating technologies. These products claim to be "antimicrobial solid surfaces," which creates significant confusion with registered copper alloy metal surfaces. Further confusion is engendered as these coating proponents often cite the EPA registration for Antimicrobial Copper Alloys to support their claims.

CDA questions the potential efficacy of these coatings technologies, for a number of sound scientific reasons. The antimicrobial properties of copper-based alloys are inherent to the solid metal surfaces. The effectiveness of copper particles is not necessarily the same as solid, copper alloy surfaces. Independent testing also has confirmed inconsistent effectiveness of copper-based coatings.

Chemical and thermal deposition processes are capable of depositing thin films of metallic copper onto various substrates. However, these surface chemistries are highly variable which minimizes the possibility of consistent performance and complicates traceability of the active ingredient.

Durability is also a concern for coating applications as repeated use can wear the entire coating away, or at minimum, reduce the amount of active copper particles on the surface. Solid copper alloys have homogenous compositions that are tightly controlled by industry standards. Registered alloys designated by the Unified Numbering System and ASTM standards demonstrate consistent antimicrobial performance throughout the thickness of the materials. Compositions of registered copper alloys are also consistent to multiple decimal places across the supply chain which ensures products will perform as advertised independent of the source. There are no such control measures for coatings and platings.

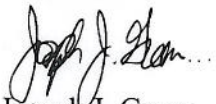
EPA should consider these factors in evaluating coating technologies and assessing any efficacy that may be produced in support of public health claims for these products.

* * * *

For the foregoing reasons, CDA requests that EPA take forceful and immediate action to prevent Cupron and EOS from continuing to make unregistered public health claims for their products. These FIFRA violations are egregiously misleading and pose substantial risks to consumers and those that rely on these claims in the erroneous belief that the Cupron and EOS products offer protection from disease-causing organisms. CDA has spent years and millions of dollars generating valid, EPA-approved data that demonstrate efficacy against a number of bacteria of public health concern and have committed to proper stewardship of these products. Cupron, EOS, and the many other purveyors of "treated articles" that make unregistered public health claims should be held to the same standard.

We appreciate your prompt attention to this matter. If you have any questions or would like additional information, please do not hesitate to contact me at 202.342.8849 or JGreen@KelleyDrye.com.

Respectfully submitted,



Joseph J. Green
Counsel to the Copper Development Association

Attachments